5th November 2018

Quality & Regulatory Affairs Manager

Company Background:

Magnetica is a Queensland-based biomedical engineering and technology company specialising in next generation Magnetic Resonance Imaging (MRI) sub-systems. We have developed and patented technology that allows smaller, lighter, faster and cheaper MRI systems to be built. Magnetica makes next generation MRI systems possible; we evolve and productise high field MRI sub-systems to create new capabilities in the medical imaging industry.

The opportunity:

We are recruiting for a motivated and focused Quality & Regulatory Affairs Manager to join our Brisbane based team. A permanent, full-time position reporting to the CEO, the role will appeal to someone looking to take the next step in their career.

Responsible and accountable for the Quality and Regulatory aspects of our business, this role will champion the development of these key capabilities within our organisation and support the CEO to drive the enabling cultural change through the organisation. As a small but growing company, this role provides the opportunity to directly influence our growth and success as we commercialise and deliver market-disrupting and regulatory compliant medical-device products.

Primary responsibilities and activities of the role include:

- Being the internal champion for implementing, obtaining and retaining certifications, maintaining effectiveness and continuously improving Magnetica's Quality Management System (QMS) in accordance with ISO 13485:2016, 21 CFR Part 820, and other applicable regulatory jurisdictions;
- Being the Management appointed representative in terms of Magnetica's QMS;
- Working with Magnetica's technical domain experts, Program Manager, Production Supervisor (to be appointed) and wider team, to ensure the timely delivery of market ready, regulatory compliant and competitive product offerings throughout the phases of Product Realisation, post-market surveillance, and the overall product lifecycle;
- Being the primary liaison/point-of-contact for day-to-day matters in relation to Magnetica's Authorised Representatives and regulatory authorities in jurisdictions where product will be marketed; and
- Other duties as agreed with the CEO from time-to-time.

Your existing capabilities and skills will include:

- Accuracy, attention to detail and a focus on task completion (a finisher);
- Being self-driven with good time management and prioritisation skills;
- Good verbal and written communication skills;
- The ability to successfully collaborate with technical and non-technical staff;
- Being a team player that can also ensure individual workload is successfully delivered;
- A willingness and ability to take on non-core tasks to support team goals;

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- Computer skills with competence in the use of Microsoft Office applications (Outlook, Word and Excel);
- Proven problem-solving abilities and a willingness to learn and apply new skills; and
- A flexible approach to dealing with changing priorities and demands.

Your experience and qualifications to meet the requirements of the role will include:

- 8+ years of Quality Assurance and/or Regulatory Affairs experience within the medical device/biotech industry;
- Demonstrated experience of successfully leading and influencing individuals and teams to embrace and support the delivery of regulatory compliant product within a QMS work environment;
- A demonstrated history of delivering high quality work, on-time, and to specifications;
- Relevant qualification(s) in field(s) of Quality, Regulatory, Engineering and/or Biotech/Medtech;
- Working successfully within an ISO 13485 and/or 21 CFR Part 820 accredited organisation;
- Relevant auditing experience, ideally including a qualification or having received external training;
- Experience in management of design controls, collation of clinical evidence and transfer to manufacturing;
- Working within a supply-chain to ensure timely downstream delivery, and upstream supply, of quality assured parts and products to meet customer needs;
- A history of safe work practices; and
- Australian citizen, permanent resident or existing holder of appropriate visa to be able to work and live in Australia.

If this role sounds like a good or great fit with your capabilities and experience, check out our website at www.magnetica.com and then apply in writing via Seek or LinkedIn, including your resume and a cover letter that addresses the criteria listed above.

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